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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/018,452	10/25/2002	Julia Elizabeth Thompson	28111/37903	4408

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EXAMINER	
TUNGATURTHI, PARITHOSH K	
ART UNIT	**PAPER NUMBER**
1643	

DATE MAILED: 09/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/018,452	THOMPSON ET AL.	
	Examiner	Art Unit	
	Parithosh K. Tungaturthi	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-37 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-37 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

S.d.o

DETAILED ACTION

1. It is noted that claims 14-20 consist of the term "use" and for the purposes of this restriction/election, it is considered as a "method of treatment".

Election/Restrictions

2. Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

To have a general inventive concept under PCT rule 13.1, the inventions need to be linked by a special technical feature. The special technical feature recited in claim 6 is an isolated specific binding member capable of binding TGFβ1, wherein said specific binding member comprises the JT182 VH domain substantially set out in SEQ ID NO:10. In view of this Thompson et al (WO97/13844, Publication Date April 17, 1997; IDS - 30 October, 2001; please see the attached sequence search) reads on the claim. Thompson et al teach a antigen binding domain (see figure 1a) of human antibody to transforming growth factor 1 or 2, that is 92.9% identical to SEQ ID NO:10. Since the claim is drawn to a specific binding pair member "substantially set out as" SEQ ID NO:10 and the exact meaning of "substantially set out as" is not clear, the antigen binding domain as taught by Thompson et al, which is 92.9% identical to SEQ ID NO:10, would read on the specific binding pair member as claimed in claim 6. Therefore the technical feature recited in claim 6 is not special. Accordingly the groups are not so linked as to form a single general concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-20, drawn to an isolated specific binding member capable of binding TGFβ1 and a pharmaceutical composition comprising such.

Group II, claim(s) 21, 22 and 28, drawn to a method of treating a condition in a patient, the condition being associated with expression of TGFβ1.

Group III, claim(s) 23, drawn to a method of determining the amount of TGFβ1 in a sample.

Group IV, claim(s) 24, 25, 27 and 33-37, drawn to an isolated nucleic acid.

Group V, claim(s) 26, drawn to a method for obtaining an antibody antigen binding domain specific for TGFβ1.

3. The inventions listed as Groups I-IX do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: As set forth above, in view of the teaching of Thompson et al the groups are not so linked as to form a

single general concept under PCT Rule 13.1 because the technical feature of claim 1 is not special.

The antibody of Group I and the nucleic acid molecule of Group IV represent separate and distinct products which are made by materially different methods, and are used in materially different methods which have different modes of operation, different functions and different effects. Polypeptides, such as the antibody of Group I which are composed of amino acids, and the product of Group IV, which are composed of nucleic acids, are structurally distinct molecules; any relationship between a polynucleotide and polypeptide is dependent upon the information provided by nucleic acid sequence open reading frame as it corresponds to the primary amino acid sequence of the encoded polypeptide. In the present claims, a polynucleotide of Group IV will not encode an antibody of Group I, and the antibody of Group I cannot be encoded by a polynucleotide of Group IV. Therefore, the antibody and polynucleotide are patentably distinct. The examination of all groups would require different searches in the U.S. Patent shoes and the scientific literature and would require the consideration of different patentability issues. Thus the inventions I and IV are patentably distinct.

The methods of Inventions II, III and V differ in the method objectives, method steps and parameters and in the reagents used. Group II recites a method of treating a condition in a patient, the condition being associated with expression of TGFβ1, Group III recites a method of determining the amount of TGFβ1 in a sample and Group V recites a method for obtaining an antibody antigen binding domain specific for TGFβ1. The examination of all groups would require different searches in the U.S. PATENT

shoes and the scientific literature and would require the consideration of different patentability issues. Thus Inventions II, III V and VI are separate and distinct in having different method objectives, method steps and parameters and in the reagents used and are patentably distinct.

Inventions I and (II, III and V) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Group I can be used in a materially different method such as immunoblot analysis in addition to the materially different methods of Groups II, III and V.

Election of species within Group I

4. This application contains claims directed to the following patentably distinct species of the claimed invention I

If group I is elected, the applicant is required to elect:

One species for Vh CDR3 from the following list:

Species a) SEQ ID NO:13

Species b) SEQ ID NO:14

"AND"

One species for Vh from the following list:

Species c) SEQ ID NO:4

Species d) SEQ ID NO:10

"AND"

One species for VI from the following list:

Species e) SEQ ID NO:6

Species f) SEQ ID NO:8

"AND"

One species and "if species O is elected, please elect a subspecies" from the following list:

Species g) glomerulonephritis

Species h) keloid

Species i) hypertrophic scarring

Species j) proliferative vitreoretinopathy

Species k) glaucoma drainage surgery

Species l) corneal injury

Species m) contracts

Species n) immune response

Species o) inflammatory response

Species p) tumour

Subspecies pa) angiogenesis

Subspecies pb) metastasis

Subspecies pc) breast

Subspecies pd) prostate

Subspecies pe) ovarian

Subspecies pf) stomach

Subspecies pg) colorectal

Subspecies ph) skin

Subspecies pi) lung

Subspecies pj) cervical

Subspecies pk) bladder tumour

Subspecies pl) leukemia

Subspecies pm) sarcoma

Species q) asthma

"AND"

One species from the following list:

Species r) excipient

Species s) carrier

Species t) buffer

Species u) stabiliser

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 4 and 10-21 are generic.

The species discussed above patentably distinct because of their distinct properties including their structure and function.

Election of species within Group II

5. This application contains claims directed to the following patentably distinct species of the claimed invention II

If group II is elected, the applicant is required to elect one species and "if species j is elected, please elect a subspecies" from the following list:

Species a) glomerulonephritis

Species b) keloid

Species c) hypertrophic scarring

Species d) proliferative vitreoretinopathy

Species e) glaucoma drainage surgery

Species f) corneal injury

Species g) contracts

Species h) immune response

Species i) inflammatory response

Species j) tumour

Subspecies ja) angiogenesis

Subspecies jb) metastasis

Subspecies jc) breast

Subspecies jd) prostate

Subspecies je) ovarian

Subspecies jf) stomach

Subspecies jg) colorectal

Subspecies jh) skin

Subspecies ji) lung

Subspecies jj) cervical

Subspecies jk) bladder tumour

Subspecies jl) leukemia

Subspecies jm) sarcoma

Species k) asthma

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 4 and 10-21 are generic.

The species discussed above patentably distinct because of their distinct properties including their structure and function.

6. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims

are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

7. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper. Furthermore, because these inventions are distinct for the reasons given above and the search required for one group is not required for another group, restriction for examination purposes as indicated is proper.

8. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. Process claims that depend from or otherwise include all the limitations of the patentable product will be entered as a matter of right if

the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. Failure to do so may result in a loss of the right to rejoinder. Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Parithosh K. Tungaturthi whose telephone number is 571-272-8789. The examiner can normally be reached on Monday through Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms, Ph.D. can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

11. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Respectfully,
Parithosh K. Tungaturthi, Ph.D.
Ph: (571) 272-8789

LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER